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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/489,079	01/21/2000	Patricia A. Billing-Medel	6451.US.P1	5338

23492 7590 09/15/2004

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EXAMINER

ASHEN, JON BENJAMIN

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 09/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/489,079

Applicant(s)

BILLING-MEDEL ET AL.

Examiner

Jon B. Ashen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 52-61, 69 and 77-81 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 52-61, 69 and 77-81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is/ objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

1. Claims 52-61, 69 and 77-81 are pending in this application. Applicant has canceled claims 62-68 and 70-76.

Claim Rejections - 35 USC § 112

2. Claims 57-58, 61, 77-79 and 81 remain rejected under 35 U.S.C § 112, 1st paragraph as failing to comply with the written description requirement for the reasons of record set forth in the prior Office action of 3/24/2004.

Response to Arguments

3. Applicant's arguments filed 6/24/2004 with respect to the rejection of record under 35 U.S.C §112 1st have been fully considered but they are not persuasive. Applicant traverses the instant rejection on the grounds that the specification adequately describes the polypeptides encompassed within the scope of the invention being claimed because Applicant has provided the complete structure of the claimed polypeptides as demonstrated by SEQ ID NOS: 24-28. (pg. 8, last paragraph, sentence continues to the top of page 9). However, as set forth in the prior Office action of 3/24/2004, the specification and claims do not place any limit on the number of amino acid substitutions, deletions, insertions and/or additions that may be made to the claimed

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polypeptides, it is only required that a BS322 polypeptide contains at least 50% identity to the polypeptide sequences according to SEQ ID NOS: 24-28.

Applicant has therefore not provided the complete structure of a BS322 polypeptide contains at least 50% identity to the polypeptide sequences according to SEQ ID NOS: 24-28.

Applicant also contends that one of ordinary skill in the art would clearly recognize that Applicant had possession of the claimed invention because the level of skill in the area of molecular biology is considerably high such that after review of Applicant's specification, one of ordinary skill in the art would recognize that Applicants have provided an adequate written description of the variants, substitutions, deletions and/or additions encompassed by the claims. However, as was set forth in the prior Office action, the general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is required. The genus of polypeptides as claimed, is highly variant as per Applicants disclosure on page 30 of the instant specification. The disclosure, however, fails to provide the relevant, identifying characteristics of the genus as claimed, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.

Applicants also argue that insufficient factual evidence is presented by the Examiner to rebut the presumption of inadequate description and that the Examiner fails to present any factual evidence as to why a person of ordinary

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skill in the art would not recognize in Applicants disclosure, a description of the invention as defined by the claims.

Applicant's attention is drawn to the MPEP §2163, which states, "The fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., Vas-Cath, Inc., 935 F.2d at 1563-64, 19 USPQ2d at 1117." It is pointed out to Applicant that factual evidence was presented by the Examiner in regards to the lack of written description wherein it was set forth in the prior Office action that no common structural attributes were set forth which would provide the required common function shared among the members of the claimed genus of polypeptides such that one of skill in the art could clearly distinguish members of this genus.

4. Applicant's arguments, see page 6, 4th paragraph, filed 6/24/2004, with respect to the rejection of claims 77-78 under 35 U.S.C. §112 2nd paragraph have been fully considered and are persuasive. The rejection of record has been withdrawn.

Claim Rejections - 35 USC § 101

5. The rejection of claims 52-61, 69 and 77-81 under 35 U.S.C § 101 and 112 is maintained for the grounds of rejection set forth in the prior Office action, mailed 3/24/2004.

Response to Arguments

6. Applicant's arguments filed 6/24/2004 have been fully considered but they are not persuasive.

Applicant argues that the basis of the Examiner's rejection stating that Jaeger et al. disclose splice variants of NY-BR-1 that are highly similar to each other is unclear (pg 11, 2nd paragraph). The following rationale is presented as clarification. As set forth in the prior Office action and as pointed out by Applicant in the instant communication, the NY-BR-1 splice variants of Jaeger et al. are highly similar, differing by only 111 bp. Applicant has argued previously that, based on nucleotide similarity, BS322 is a splice variant of NY-BR-1 (communication filed 11/06/2003, pg 3). However, it is noted herein that the nucleotide sequence of BS322 is disclosed as 2683 base pairs in length while the nucleotide sequence of NY-BR-1 is disclosed as 4463 base pairs in length. Given the large length differences between these two molecules as compared to the differences observed between NY-BR-1 and the known NY-BR-1 splice variants of Jaeger et al., sound scientific reasoning dictates that specific and particular evidence of the alternative splicing and maturation of a splice variant that is the considerably shorter BS322 nucleotide sequence (as compared to NY-BR-1) would be required to demonstrate that BS322 was indeed a splice variant of NY-BR-1.

Applicant also contends that they are not required to show that the claimed polypeptides are derived from both [*splice*] variants, if both variants are linked to breast disease but that Applicant is required only to show that the

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claimed polypeptides are derived from one polynucleotide which is linked to breast disease (pg 11, 2nd paragraph). This argument is moot however, because applicant is required to show that the claimed polypeptides are useful in the method of the invention as claimed and applicant has not shown how BS322 is a polynucleotide that is linked to breast disease.

Applicants also contend that the specification clearly shows how SEQ ID NOS: 24-28 are derived from a polypeptide that is shown to be linked to breast disease (pg. 11, last sentence). However, it is respectfully pointed out that SEQ ID NOS: 24-25 are different polypeptides derived from alternative translations of a single polynucleotide (SEQ ID NO: 9), as disclosed on page 64 of the instant specification. In the instant case it is not clear how different polypeptides, translated from different but overlapping reading frames, can be derived from a single polypeptide. Additionally, no evidence is presented for a single polypeptide that is shown to be linked to breast disease in view of the Jaeger et al. reference. Therefore, Applicant has presented no evidence that SEQ ID NOS: 24-28 are derived from a single polypeptide that has been shown to be linked to breast disease.

Applicants also argue, with respect to the previous grounds of rejection that considers that Applicant has not provided objective evidence that the individual peptides according to SEQ ID NOS: 24-28 represent actual NY-BR-1 antigen epitopes, that the description of epitopes, a structural feature of the claimed polypeptides, is not easily describable by words (pg. 12, 2nd and 3rd paragraphs). Therefore, Applicant submits that the significance of the structure

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of the polypeptides are described via their SEQ ID NO: as allowed in the Eli Lilly cases discussed in the USPTO Written description guidelines. Applicant's attention is drawn to MPEP § 2163 which states that the written description requirement may be satisfied through disclosure of function and minimal structure when there is a well-established correlation between structure and function. In contrast, without such a correlation, the capability to recognize or understand the structure from the mere recitation of function and minimal structure is highly unlikely. In this latter case, disclosure of function alone is little more than a wish for possession; it does not satisfy the written description requirement. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. In the instant case, Applicant has not provided adequate written description of the epitopes of the invention because there is no disclosure of a structure-function relationship between the sequences of the polypeptides claimed that are SEQ ID NOS: 24-28 and the function of these sequences as epitopes. Rather, applicant has provided a mere recitation of function and minimal structure (as presented by primary sequence data depicted in contiguous strings of amino acid or nucleobase residues that are represented in U.S. Patent documents by SEQ ID NO:), which does not provide adequate written description. Therefore, applicants argument that the significance of the structure of the polypeptides of SEQ ID NO: 24-28 is described via their primary sequence does not overcome the grounds of the rejection of record because it does not provide objective evidence that the individual peptides according to SEQ ID NOS: 24-28 represent actual NY-BR-1 antigen epitopes.

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Applicant further argues that their disclosure, in describing methods such as complex formation of immunogenic specific binding members using the claimed polypeptides and disclosing the exact amino acid sequences of polypeptides according to SEQ ID NOS: 24-28 provides objective evidence that demonstrates that the individual peptides according to SEQ ID NOS: 24-28 represent actual NY-BR-1 antigen epitopes (pg. 13, 2nd paragraph). Applicant points to *Noelle v. Lederman* (69 USPQ2d 1481 (CAFC 2004)) where the court held that a claim directed to an antibody which is capable of binding to a particular antigen has sufficient support in the written description that discloses "fully characterized" antigens. However, the finding of the Court in the above case considers that sufficient support in the written description relies on "fully characterized" antigens. In the instant case, applicant's antigens are not fully characterized for the reasons set forth in the preceding paragraph. Therefore, because applicant does not have adequate written description of the particular BS322 antigens to which an antibody is capable of binding, sufficient support is not present for claims to said antibody.

Lastly, Applicant argues that their claims are not drawn to a method of directly curing diseases of the breast although the claimed methods of detection of antibodies ultimately can be useful in treating diseases of the breast (pg. 13, 3rd paragraph). This argument is moot because the rejection of record considers that one of skill in the art would not accept on its face that applicant has provided any sufficient objective evidence for the asserted utility of the claimed

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polypeptides as breast specific antigens that are useful as diagnostics for breast disease.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon B. Ashen whose telephone number is 571-272-2913. The examiner can normally be reached on 7:30 am - 4:30 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Jba



SEAN MCGARRY
PRIMARY EXAMINER
1635